

Attorney's Docket No. MPI1998-067CP1CN. (M)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Sophie Lehar, Stephen Manning, Anthony J. Coyle, Jose-Carlos Gutierrez-Ramos
Application No.: N/A Group No.: ***Not Assigned***
Filed: Herewith Examiner: ***Not Assigned***
For: NOVEL TH2-SPECIFIC MOLECULES AND USES THEREOF

Assistant Commissioner for Patents
Washington, D.C. 20231

PATENT

1c978 U.S. PTO
09/989545



TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
WITHIN THREE MONTHS OF FILING OR
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. section 1.97(b))

Transmitted herewith are:

- ☒ Transmittal letter (1 page)(in duplicate).
- ☒ Information Disclosure Statement (3 pages).
- ☒ Form PTO/SB/08A (1 page).
- ☒ Form PTO/SB/08B (2 pages).
- ☒ 9 References.

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING
INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

Express Mail" mailing label number <u>EL791759296US</u>	MILLENNIUM PHARMACEUTICALS, INC.
Date of Deposit <u>November 20, 2001</u>	
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Box Sequence, Washington, D.C. 20231	
Signature <u><i>Sean Hunziker</i></u>	By <u><i>Kerri Pollard Schray</i></u>
Please Print Name of Person Signing <u>Sean Hunziker</u>	Kerri Pollard Schray Registration No.: 47,066 Agent for Applicants Millennium Pharmaceuticals, Inc. 75 Sidney Street Cambridge, MA 02139 Telephone: 617-551-3676 Facsimile: 617-551-8820

Attorney's Docket No. MPI1998-067CP2CN1A(M)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT



In re application of: Sophie Lehar, Stephen Manning, Anthony J. Coyle, Jose-Carlos Gutierrez-Ramos

Application No.: N/A

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For: NOVEL TH2-SPECIFIC MOLECULES AND USES THEREOF

Group No.: ***Not Assigned***

Examiner: ***Not Assigned***

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

1. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)
2. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
3. Copies of Listed Information Items Accompanying This Statement
4. Identification of Person(s) Making This Information Disclosure Statement

Section 1. Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)

(Insert form(s) PTO/SB/08A [Form 6-2] and/or form(s) PTO/SB/08B [Form 6-2.1].)

Section 2. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted

This application relies, under 35 U.S.C. section 120, on the earlier filing date of prior application USSN.: 09/413,136, filed on October 6, 1999.

This application also relies, under 35 U.S.C. section 120, on the earlier filing date of prior application USSN: 09/258,670, filed on February 26, 1999.

This application also relies, under 35 U.S.C. section 120, on the earlier filing date of prior application USSN 09/168,229, filed on October 7, 1998.

The following references were submitted to, and/or cited by, the Office in the prior applications and, therefore, are not required to be provided in this application:

US 5,783, 182	Baylor College of Medicine	07/21/1998
WO 98/38216	Japan Tobacco Inc.	09/03/1998
WO 98/39448	Human Genome Sciences, Inc.	09/11/1998
WO 98/45437	Genetics Institute, Inc.	10/15/1998
WO 99/07727	Massachusetts Institute of Technology	02/18/1999
WO 99/09049	Quark Biotech, Inc. et al.	02/25/1999
WO 99/46281	Genentech, Inc.	09/16/1999

ROBINSON et al., Predominant TH2-Like Bronchoal Veolar T-Lymphocyte Population in Atopic Asthma, The New England Journal of Medicine, January 30, 1992, 298-304, Vol. 326(5), USA

ROMAGNANI, S., Induction of TH1 and TH2 Responses: A Key Role for the 'Natural' Immune Response?, Immunology Today, 1992, 379-381, Vol. 13(10), Elsevier Science Publishers Ltd., United Kingdom

DEL PRETE et al., Allergen Exposure Induces the Activation of Allergen-specific Th2 Cells in the Airway Mucosa of Patients with Allergic Respiratory Disorder, European Journal of Immunology, 1993, 1445-1449, Vol. 23, VCH Verlagsgesellschaft mbH, Weinheim

TAO et al., Strength of TCR Signal Determines the Costimulatory Requirements for Th1 and Th2 CD4+ T Cell Differentiation, The Journal of Immunology, 1997, 5956-5963, The American Association of Immunologists.

NICOLAIDES et al., Interleukin 9: A Candidate Gene for Asthma, Proc. Natl. Acad. Sci. USA, November 1997, 13175-13180, Vol. 94, Medical Sciences.

MORIGGL et al., Activation of STAT Proteins and Cytokine Genes in Human Th1 and Th2 Cells Generated in the Absence of IL-12 and IL-4, The Journal of Immunology, 1998, 3385-3392, The American Association of Immunologists.

PADRID et al., CTLA4Ig Inhibits Airway Eosinophilia and Hyperresponsiveness by Regulating the Development of Th1/Th2 Subsets in a Murine Model of Asthma, American Journal of Respiratory Cell and Molecular Biology, 1998, 453-462, Vol. 18, USA

SMITH et al., Partial TCR Signals Delivered by FcR-Nonbinding Anti-CD3 Monoclonal Antibodies Differentially Regulate Individual Th Subsets, The Journal of Immunology, 1998, 4841-4849, The American Association of Immunologists.

DATABASE GenBank on STN Accession No. AA21744, MARRA et al., T wash U-HHM1 Mouse EST Project, January 21, 1997

HUANG, S-K, Molecular Modulation of Allergic Responses, J. Allergy Clin. Immunol., December 1998, 887-892, Vol. 102

GAP Alignment of h1419 vs. V59728 in WO 98/39448

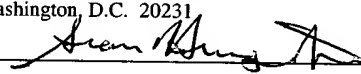
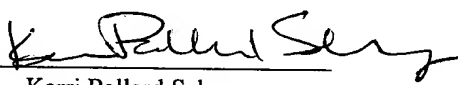
Section 3. Copies of Listed Information Items Accompanying This Statement

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement except these listed in Section 2.

*****IF GF6-1 Language Listed Info = "EPO Search Report"*****IF GF6-1 Language Listed Info = "English Language Version of EPO Search Report"****Section 4. Identification of Person Making This Information Disclosure Statement**

The person making this certification is:

- a. the practitioner who signs below on the basis of the information in the practitioner's file.

<p>Express Mail" mailing label number <u>EL791759296US</u></p> <p>Date of Deposit <u>November 20, 2001</u></p> <p>I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231</p> <p> Signature</p> <p><u>Sean Hunziker</u> Please Print Name of Person Signing</p>	<p>MILLENNIUM PHARMACEUTICALS, INC.</p> <p>By  Kerri Pollard Schray Registration No.: 47,066 Agent for Applicants Millennium Pharmaceuticals, Inc. 75 Sidney Street Cambridge, MA 02139 Telephone: 617-551-3676 Facsimile: 617-551-8820</p>
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Complete if Known

Application Number	N/A
Filing Date	11/21/2001
First Named Inventor	Sophie Lehar et al

(use as many sheets as necessary)

Sheet	1	of	1
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Examiner Name	
Attorney Docket Number	MPI1998-067CP2CN1A(M)

100-443887-100

11/20/01

[illegible][illegible]Date
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Application Number	N/A
Filing Date	11/20/2001
First Named Inventor	Sophie Lehar et al
Group Art Unit	
Examiner Name	
Attorney Docket Number	MP11998-067CP2CN1A(M)

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Sheet 1 of 2

Examiner Initials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	11	ROBINSON ET AL., "Predominant TH2-Like Bronchoalveolar T-Lymphocyte Population in Atopic Asthma," The NE Journal of Medicine, Vol. 326 (No. 5), p. 298-304, (January 30, 1993).	
	12	ROMAGNANI, S., "Induction of TH1 and TH2 Responses: A Key Role for the 'Natural' Immune Response?," Immunology Today, Elsevier Science Publishers Ltd. United Kingdom, Vol. 13 (No. 10), p. 379-381, (November 20, 1992).	
	13	DEL PRETE ET AL., "Allergen Exposure Induces the Activation of Allergen-specific Th2 Cells in the Airway Mucosa of Patients with Allergic Respiratory Disorder," European Jour of Immunology, p. 1445-1449, (November 20, 1993).	
	14	TAO ET AL., "Strength of TCR Signal Determines the Costimulatory Requirements for Th1 and Th2 CD4+ T Cell Differentiation," The Jour of Immunology, p. 5956-5963, (November 20, 1997).	
	15	NICOLAIDES ET AL., , "Interleukin 9: A Candidate Gene for Asthma," Proc. Natl. Acad. Sci., p. 13175-1318, (November 20, 1997).	
	16	MORIGGL ET AL., "Activation of STAT Proteins and Cytokine Genes in Human Th2 and Th2 Cells Generated in the Absence of IL-12 and IL-4," The Jour of Immunology, p. 3385-3392, (November 20, 1998).	
	17	PADRID ET AL., "CTLA4Ig Inhibits Airway Eosinophilia and Hyperresponsiveness by Regulating the Development of Th1/Th2 Subsets in a Murine Model of Asthma," Amer Jour of Respiratory Cell and Molecular Biology, p. 453-462, (November 20, 1998).	
	18	SMITH ET AL., "Partial TCR Signals Delivered by FcR-Nonbinding Anti-CD3 Monoclonal Antibodies Differentially Regulate Individual Th Subsets," The Jour of Immunology, p. 4841-4849, (November 20, 1998).	
	19	DATABASE GENBANK ON STN ACCESSION NO. AA21744, MARRA ET AL., T WASH U-HHMI MOUSE EST PROJECT, ", (January 21, 1997).	
	20	HUANG, S-K, "Molecular Modulation of Allergic Responses," J. Allergy Clin. Immunol., p. 887-892, (December 20, 1998).	
	21	GAP Alignment of h1419 vs. V59728 in WO 98/39448	

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	N/A
		Filing Date	11/20/2001
		First Named Inventor	Sophie Lehar et al
		Group Art Unit	
		Examiner Name	
Sheet 2 of 2	Attorney Docket Number	MPI1998-067CP2CN1 (M)	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	22	HUTLOFF, A. ET AL, "ICOS is an inducible T-Cell co-stimulaor structurally and functionally related to CD28," Nature, p. 263-266, (January 21, 2000).	
	23	BUONFIGLIO, D. ET AL, "The T Cell Activation Molecule H4 and the CD28-Like Molecule ICOS are Identical," Eur. J. Immunol., p. 3463-3467, (November 20, 2000).	
	24	BUONFIGLIO, D. ET AL., "Characterization of a Novel Human Surface Molecule Selectively Expressed by Mature Thymocytes, Activated T Cells and Subsets of T Cell Lymphomas," Eur. J. Immunol., p. 2863-2874, (November 20, 1999).	
	25	REDOGLIA, V., ET AL., "Characterization of H4: A Mouse T Lymphocyte Activation Molecule Functionally Associated with the CD3/T Cell Receptor," Eur. J. Immunol., p. 2781-2789, (November 20, 1996).	
	26	GONZALO, J. ET AL., "ICOS is Critical for T Helper Cell-Mediated Lung Mucosal Inflammatory Responses," Nature Immunology, Vol. 2 (No. 7), p. 597-604, (July 20, 2001).	
	27	ROTTMAN, J. ET AL., "The Costimulatory Molecule ICOS Plays an Important Role in the Immunopathogenesis of EAE," Nature Immunology, Vol. 2 (No. 7), p. 605-611, (July 20, 2001).	
	28	OZKAYNAK, E. ET AL., "Importance of ICOS-B7RP-1 Costimulation in Acute and Chronic Allograft Rejection," Naure Immunology, Vol. 2 (No. 7), p. 591-596, (July 20, 2001).	

Examiner Signature		Date Considered	
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